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PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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September 15, 2004

Michael Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building (1101A)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Comments on Chevron Phillips Asphalt, sulfonated, sodium salt test plan

Dear Administrator Leavitt:

The following comments on Chevron Phillips Chemical Company's Asphalt, sulfonated, sodium salt (SAS) HPV test plan are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The SAS plan presents a review of the chemistry and toxicity of these non-toxic, non-bioavailable compounds and relates that chemistry to several existing categories in the HPV program. However, the plan is confusing and falls far short of realizing the full potential of a structure-activity analysis by calling for an additional combined repeat dose/reproductive/ developmental test of the material. If conducted, this test will kill another 675 animals.

In addition, the test plan presented is a "Sanitized Public Copy" with additional issues presented in the EPA's copy. The context of the sanitization suggests that the edited comments are focused on the aromatic composition of the substance, which may well be the most bioactive portion and the most likely to cause any toxicity.

As clearly described in the test plan, SAS is a high-molecular-weight substance derived from asphalts. While Chevron Phillips has described the overall general character of these compounds, including detailed information on the molecular weight distribution, chemical/physical properties, physical modeling, and the results of fugacity modeling, the company includes absolutely no information on the specific chemical compounds that comprise the substance, other than to state that it is "an asphalt-based complex alkyl aromatic hydrocarbon mixture." Specifically, no information is provided on the polyaromatic hydrocarbon content of these "complex" substances. We are only provided hints on the exact composition. For instance, despite the characterization of these compounds as being simply sulfonated organic compounds (Table 3), napthenic acids are also included in the surrogate list, which are "predominantly...compounds that contain carboxylic acid functional groups and five-to-six member naphthenic rings in their molecular structures." Nowhere else in the test plan is the compositional link to naphthenic acid mentioned nor is the presence of carboxyl groups mentioned. Again, is there information missing from the test plan on the detailed aromatic composition of these compounds? Considering the potential health effects of napthenic acid, clarification of this point is extremely important.

Chevron Phillips has clearly linked the composition of SAS to several other categories that have been thoroughly studied, and/or are currently undergoing analysis in the HPV Program. As SAS has a higher molecular weight range than any of these other categories, with the exception of asphalts, and this higher molecular weight range will limit the bioavailability and solubility of the compounds, it seems that SAS should have been included in these other categories with no further testing proposed. It is clear that the overall toxicity of SAS is low and simply due to molecular weight exclusion, and it is unlikely that the material is absorbed by mammals.

In fact, the acute toxicity data provided in the robust summaries demonstrate that the substance is non-toxic at the limit dose. While repeat-dose data are summarized for the SAS surrogates, no information on the studies is provided in the robust summary, and we are therefore unable to determine whether any of the repeat-dose studies included evaluations of the reproductive organs. Data on histopathology of reproductive organs from repeated dose studies, combined with data from the developmental study, can be used to meet the SIDS endpoint for reproductive toxicity without conducting additional animal tests.

Further, Chevron Phillips contradicts itself when it states that "no reproductive or developmental toxicity studies were identified for SAS or any of its structural surrogates," but then goes on to state that a reproductive study was conducted for napthenic acid (test plan, page 28). Without explanation, Chevron Phillips then states that this reproductive study was "not of sufficient data quality and was in abstract form only." The reference provided in support of this statement is the American Petroleum Institute's 2003 HPV test plan for reclaimed substances, and the reproductive study listed in that robust summary comes from the EPA. It seems to us that, with a minimal amount of due diligence, information could be obtained and provided on the details of this reproductive study. With the animal testing data that already exist, it is important to carefully document and consider the chemical composition of SAS and evaluate similarities between SAS and napthenic acids.

Chevron Phillips then goes on to state that, "considering the high molecular weight, limited bioavailability, and minimal observed general toxicity of SAS, SAS is unlikely to cause developmental or reproductive effects." It is therefore all the more inexplicable why, in the following sentence, Chevron Phillips declares it will conduct testing for reproductive and developmental endpoints. This is yet another example of thoughtless, check-the-box toxicology that has characterized too many of the HPV test plans submitted to date and has led to the useless suffering and deaths of tens of thousands of animals in this program.

We ask that this sponsor adhere to the principles stated by the EPA in both the December 2000 *Federal Register* notice on the HPV program and the October 1999 letter sent to all HPV participants, in particular the following sections:

> In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.... Participants shall maximize the use of scientifically appropriate categories of related chemicals and structure activity relationships.... As with all chemicals,

before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.

In summary, we are dismayed by Chevron's withholding information and confusing approach which ends up proposing additional animal testing for a substance that is less toxic than the three surrogates on which it provided data. I can be reached at 757-622-7382, ext. 8001, or via e-mail at JessicaS@peta.org, and would appreciate hearing back from Chevron Phillips regarding our concerns.

Sincerely,

Jessica Sandler
Federal Agency Liaison